DEXTROSE AND SODIUM CHLORIDE - dextrose monohydrate and sodium chloride injection
BAXTER HEALTHCARE CORPORATION

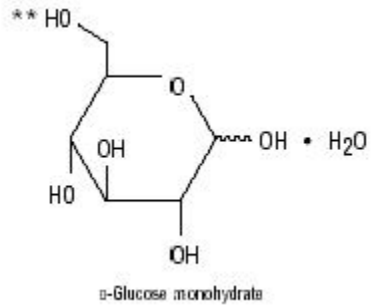
DESCRIPTION

Dextrose and Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)		*Osmolarity (mOsmol/L) (calc.)	pH	Ionic Concentration (mEq/L)		Caloric Content (kcal/L)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	500 1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85
5% Dextrose and 0.2% Sodium Chloride Injection, USP	250 500 1000	50	2	321	4.0 (3.2 to 6.5)	34	34	170
5% Dextrose and 0.33% Sodium Chloride Injection, USP	250 500 1000	50	3.3	365	4.0 (3.2 to 6.5)	56	56	170
5% Dextrose and 0.45% Sodium Chloride Injection, USP	250 500 1000	50	4.5	406	4.0 (3.2 to 6.5)	77	77	170
5% Dextrose and 0.9% Sodium Chloride Injection, USP	250 500 1000	50	9	560	4.0 (3.2 to 6.5)	154	154	170
10% Dextrose and 0.9% Sodium Chloride Injection, USP	500 1000	100	9	813	4.0 (3.2 to 6.5)	154	154	340

*****Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.



D-Glucose monohydrate

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY
Dextrose and Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE
Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

CONTRAINDICATIONS
Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS
Dextrose and Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.
Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The container label for these injections bears the statement: Do not administer simultaneously with blood.
The intravenous administration of Dextrose and Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.
Excessive administration of Dextrose and Sodium Chloride Injection, USP may result in significant hypokalemia.
In patients with diminished renal function, administration of Dextrose and Sodium Chloride Injection, USP may result in sodium retention.

PRECAUTIONS
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
Caution must be exercised in the administration of Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.
Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injection, USP. It is also not known whether Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use
Safety and effectiveness of Dextrose and Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of dextrose and sodium chloride solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.
In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage.

Carcinogenesis, mutagenesis, impairment of fertility
Studies with Dextrose and Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injection, USP is administered to a nursing mother.

Geriatric Use
Clinical studies of Dextrose and Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually

starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION
As directed by a physician. Dosage is dependent upon the age, weight, and clinical condition of the patient as well as laboratory determinations.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.
As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low weight infants, because of the increased risk of hyperglycemia/hypoglycemia.
Additives may be incompatible. Complete information is not available.
Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED
Dextrose and Sodium Chloride Injection, USP in VIAFLEX plastic container is supplied as follows:

Code	Size (mL)	NDC	Product Name
2B1023	500	0338-0073-03	2.5% Dextrose and 0.45% Sodium Chloride Injection, USP
2B1024	1000	0338-0073-04	
2B1092	250	0338-0077-02	5% Dextrose and 0.2% Sodium Chloride Injection, USP
2B1093	500	0338-0077-03	
2B1094	1000	0338-0077-04	
2B1082	250	0338-0081-02	5% Dextrose and 0.33% Sodium Chloride Injection, USP
2B1083	500	0338-0081-03	
2B1084	1000	0338-0081-04	
2B1072	250	0338-0085-02	5% Dextrose and 0.45% Sodium Chloride Injection, USP
2B1073	500	0338-0085-03	
2B1074	1000	0338-0085-04	
2B1062	250	0338-0089-02	5% Dextrose and 0.9% Sodium Chloride Injection, USP
2B1063	500	0338-0089-03	
2B1064	1000	0338-0089-04	
2B1163	500	0338-0095-03	10% Dextrose and 0.9% Sodium Chloride Injection, USP
2B1164	1000	0338-0095-04	

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open
Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish

gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING

Additives may be incompatible.

To add medication before solution administration

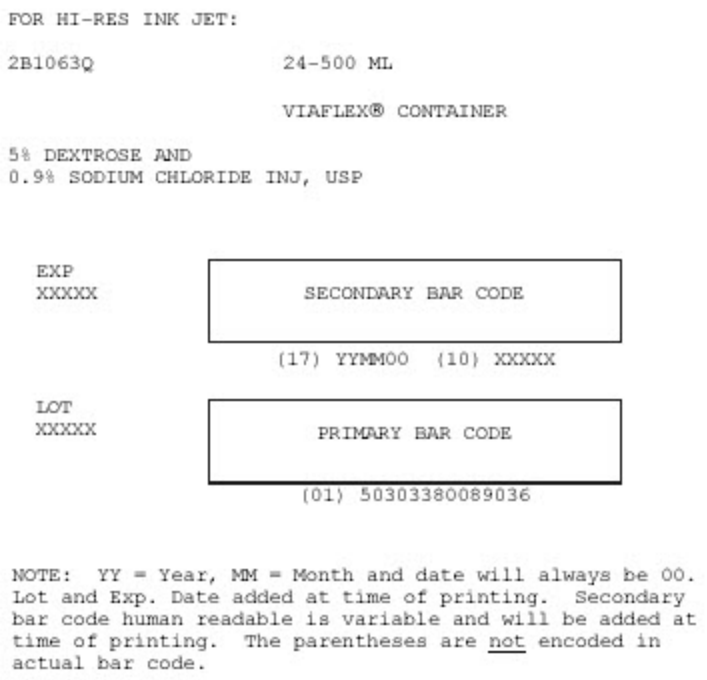
1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.

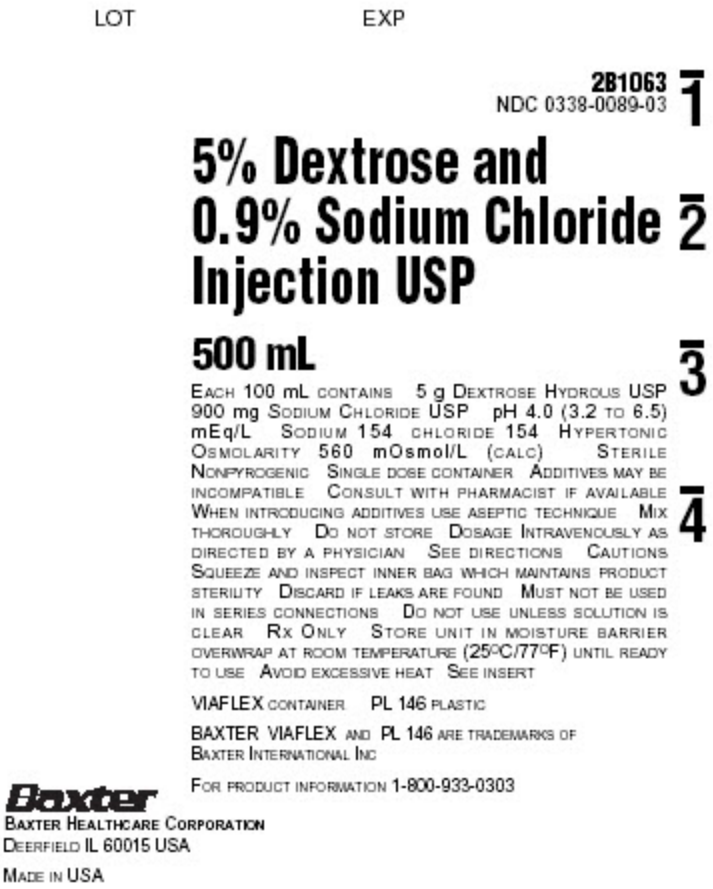
Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Printed in USA
07-19-39-749 August 2003

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



5% Dextrose and 0.9% Sodium Chloride Injection USP, 500mL Container Label

2B1063Q 24-500 ML
VIAFLEX® CONTAINER
5% DEXTROSE AND
0.9% SODIUM CHLORIDE INJ, USP
EXP
XXXXX
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
LOT
XXXXX
PRIMARY BAR CODE
(01) 50303380089036
NOTE: YY = Year, MM = Month and date will always be 00. Lot and Exp. Date added at time of printing. Secondary bar code human readable is variable and will be added at time of printing. The parentheses are not encoded in actual bar code.



5% Dextrose and 0.9% Sodium Chloride Injection USP, 500mL Carton Label

2B1063
NDC 0338-0089-03
5% Dextrose and
0.9% Sodium Chloride
Injection USP
500 mL
EACH 100 mL CONTAINS 5 g DEXTROSE HYDROUS USP
900 mg SODIUM CHLORIDE USP pH 4.0 (3.2 TO 6.5)
mEq/L SODIUM 154 CHLORIDE 154 HYPERTONIC
OSMOLARITY 560 mOsmol/L (CALC) STERILE
NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE
INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE
WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX
THOROUGHLY DO NOT STORE DOSAGE INTRAVENOUSLY AS
DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS
SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT
STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED
IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS
CLEAR RX ONLY STORE UNIT IN MOISTURE BARRIER
OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY
TO USE AVOID EXCESSIVE HEAT SEE INSERT
VIAFLEX CONTAINER PL 146 PLASTIC
BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC
FOR PRODUCT INFORMATION 1-800-933-0303
BAXTER
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA